

K011933

NOV 02 2001

510(k) Summary of safety and Effectiveness

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

**1) Submitter
name, address,
contact**

Owner/ Operator
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USA contact person

Thomas M Tsakeris

Company

Devices and Diagnostics Consulting Group Inc.

Address:

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USA

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Date Prepared

13th June 2001

2) Device name	Proprietary name: Glycosal™ II HbA _{1c} Test Common name: Prescription Home use Test for the Detection of Glycated Hemoglobin in Human Whole Blood. Classification: ASSAY, GLYCOSYLATED HEMOGLOBIN
3) Predicate Device	The Glycosal™ II HbA _{1c} test is substantially equivalent to other products in commercial distribution for similar use, including the Glycosal™ HbA _{1c} test (primary predicate device) and the Metrika DRX HbA _{1c} for prescription home use test (secondary predicate device).
4) Device Description	Instrument read, single use <i>in vitro</i> test for the quantitative determination of glycated hemoglobin (GHb) in diabetics.
5) Intended use	<p>The Glycosal™ II HbA_{1c} test is an affinity chromatography method and is intended for the in-vitro quantitative determination of HbA_{1c} in capillary blood taken from a finger prick.</p> <p>The test is indicated for use by diabetics for monitoring the time averaged blood glucose levels of known diabetics as an indicator of overall glycaemic control.</p> <p>The Glycosal™ II HbA_{1c} test is intended for use as a prescription home use test.</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Provalis Diagnostics Ltd.
c/o Mr. Thomas M. Tsakeris
Devices and Diagnostics Consulting Group
16809n Briardale Road
Rockville, MD 20855

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Re: k011933
Trade/Device Name: Glycosal™ II HbA_{1c} Test
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP
Dated: September 19, 2001
Received: September 20, 2001

Dear Mr. Tsakeris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

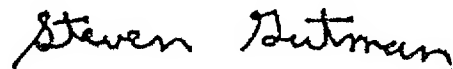
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "Steven Gutman".

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 02 2001

Intended Use/Indications for Use Statement

510(k) Number: *Unknown-not yet assigned by FDA*

Device Name: *Glycosal™ II HbA_{1c} Test*

Intended Use/Indications for Use Statement:

The Glycosal™ II HbA_{1c} assay is an affinity chromatography method and is intended for the in-vitro quantitative determination of HbA_{1c} in capillary blood taken from a finger prick.

The test is indicated for monitoring the time averaged blood glucose levels of known diabetics, for use at home by diabetics as an indicator of overall glycaemic control.

The Glycosal™ II HbA_{1c} assay is intended for prescription home use.

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE
ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Josephine Bantua
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number *K011933*